

REMARKS

The pending Office Action addresses and rejects claims 1-9 and 13-27.

Rejection Pursuant to 35 U.S.C. §103

Claims 1-4, 6, 7, 9, 13-15, and 17-26

The Examiner rejects claims 1-4, 6, 7, 9, 13-15, and 17-26 pursuant to 35 U.S.C. §103(a) as being obvious over US 2003/0032915 A1 to Saul ("Saul 915") in view of U.S. Patent 6,533,733 to Ericson et al. ("Ericson"). The Examiner asserts that Saul 915 teaches the claimed invention except for "an external system controller" that "communicates with the shunt and valve system remotely via telemetry." The Examiner relies on Ericson to teach this feature, arguing that it would have been obvious to modify the device of Saul 915 in view of Ericson to arrive at the claimed invention. Applicant respectfully disagrees.

Independent claim 1 recites a method of regulating cerebrospinal fluid flow in a hydrocephalus patient. The method includes providing an implantable shunt system having a sensor element positioned within a ventricular cavity and a selectively operable external system controller device for communicating remotely via telemetry with the shunt system. Independent claim 17 similarly recites an apparatus for regulating cerebrospinal fluid flow in a hydrocephalus patient that includes a selectively operable external system controller device for communicating remotely via telemetry with the shunt system.

As an initial matter, the Examiner incorrectly equates the programming step taught by Saul 915 with the energizing step claimed by Applicant. In commenting on arguments presented by Applicant in the Response filed July 26, 2007, the Examiner asserts that Saul 915 teaches a system that is "programmed to adjust the valve after a predetermined change in pressure is measured, rather than continuously adjusting the opening pressure." The Examiner thus concludes that this "programming" step amounts to "energizing" the valve "as a separate step of the monitoring procedure." (Office Action, pg. 6). However, as explained in paragraphs [0033] and [0035], Saul 915 teaches a system that includes an *internal* controller that is *pre-programmed* by an operator. *Pre-programming* the *internal* system controller allows for *continuous* and *automatic* operation of

the system upon implantation in the patient. In other words, Saul 915 enables the operator to “set it and forget it.” Independent claim 1, however, requires the patient or attending physician to energize the system using the external controller device each time a pressure reading is desired, for example, when the patient manifests systems of the disease. Thus, contrary to the Examiner’s assertion, *pre-programming* the *internal* controller of the Saul 915 system is not equivalent to *energizing* the shunt system with the *external* controller device, as required by claim 1

Moreover, combining Saul 915 with Ericson would not yield predictable results, as asserted by the Examiner. Applicant refers the Examiner to the “Examination Guidelines for Determining Obviousness Under 35 U.S.C 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*” (hereinafter “the Guidelines”). As explained in Section A(2) of the Guidelines, to reject a claim on the basis that combining prior art elements according to known methods yields predictable results, the Examiner must articulate:

...a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that *in combination, each element merely would have performed the same function as it did separately*; [Emphasis Added].

Combining Saul 915 with Ericson does not yield a combination where each element performs the same function as it did separately. In particular, the internal system controller of Saul 915 would function markedly different in combination with Ericson than it does separately. Specifically, Saul 915’s internal system controller could no longer be pre-programmed to automatically operate the shunt system, as the combination would require the controller to be manually energized. Thus, contrary to the Examiner’s assertion, combining Saul 915 with Ericson does not yield predictable results.

Even further, combining Saul 915 with Ericson to include a selectively operable external system controller device for communication remotely via telemetry with the system is not only unpredictable but undesirable as well. MPEP §2143.01(V) states that “[i]f the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.” As

explained above, the method and apparatus disclosed by Saul 915 require *continuously monitoring* a patient's intracranial pressure and *automatically* opening or closing a valve in order to maintain a target pressure in the ventricles over a period of time. In contrast, the method and apparatus of the claimed invention require the patient or attending physician to energize the system using the external controller device. Modifying Saul 915 to include such an external controller would render Saul 915 unsatisfactory for its intended purpose because Saul 915 could no longer continuously monitor a patient's intracranial pressure, as the system would have to be energized by an operator. No person having ordinary skill in the art would be motivated to modify a method and device aimed at continuous, automatic operation to include the intervening step of energizing. Thus, it would not have been obvious to modify Saul 915 in view of Ericson.

Accordingly, independent claims 1 and 17, as well as claims 2-16 and 18-27 which depend directly or indirectly therefrom, distinguish over Saul 915 and Ericson, taken alone or combined, and represent allowable subject matter.

Claims 5, 8, 16, and 27

The Examiner rejects claims 5, 8, 16, and 27 pursuant to 35 U.S.C. §103(a) as being obvious over Ericson in view of Saul 915 and further in view of US 2003/0004495 A1 of Saul ("Saul 495"). The Examiner asserts that Ericson and Saul 915 teach the claimed invention "with the exception of repeating the resistance adjustment procedure at proscribed time intervals" and "a timed shut-off mechanism," relying on Saul 495 to teach these features. Claims 5, 8, and 16 depend from independent claim 1 and claim 27 depends from independent claim 17. As discussed above, one skilled in the art would have no motivation to combine Ericson and Saul 915, and therefore claims 5, 8, 16, and 27 are allowable at least because they depend from allowable claims 1 and 17.

Conclusion

In view of the above amendments and remarks, Applicant submits that all claims are in condition for allowance, and allowance thereof is respectfully requested. Applicant encourages the Examiner to telephone the undersigned in the event that such communication might expedite prosecution of this matter.

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Respectfully submitted,

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